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EXAMINER

ART UNIT	PAPER NUMBER
45	

DATE MAILED: 08/26/87

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on \_\_\_\_\_  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1.  Notice of References Cited by Examiner, PTO-892. 2.  Notice re Patent Drawing, PTO-948.  
3.  Notice of Art Cited by Applicant, PTO-1449 4.  Notice of Informal Patent Application, Form PTO-152  
5.  Information on How to Effect Drawing Changes, PTO-1474 6.

Part II SUMMARY OF ACTION

1.  Claims 1-30 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been canceled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims 1-30 are rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8.  Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. These drawings are  acceptable;  not acceptable (see explanation).

10.  The  proposed drawing correction and/or the  proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been  approved by the examiner.  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved.  disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12.  Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received

been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1.A Claims 7-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-24 of copending application Serial No. 867,996.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

1B. Claims 1-6 and 25-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 25 of copending application serial no. 867,996. Although the conflicting claims are not identical, they are not patentably distinct from each other because given the generic overlap, the embodiments in one application suggest the corresponding embodiments in the other. Note, In re Lemin, 141 USPQ 814.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

1C. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

1D. The following is a quotation of the first

paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention.

2. The term "lower alkyl carboxy" is a distortion. The term should be "carboxy lower alkyl". Note, In re Hill, 73 USPQ 482.

3. Claims 1-4 and 19-25 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

4. Claims 1-4 and 19-25 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Substituted" without a recitation of substituents renders a claim indefinite and otherwise not adequately supported by the enabling disclosure as the claim is made to read on any and all manners of substitution.

Particular contemplated substituents should be incorporated.

5. In the generic description, a number of the listed groups improperly encompass other listed groups. Each of the members of a Markush recitation must be mutually exclusive. A list of the improper pairs follows:

(a) "acetoxy" and "alkanoyloxy" in the definition of "x";

(b) "lower alkyl-<sup>o</sup>c-" and "-<sup>o</sup>c-R<sub>5</sub> (R<sub>5</sub>=alkyl" in the definition of "x";

(c) R<sub>6</sub> and R<sub>7</sub> as "hydrogen" and "alkyl" is recited in two places;

(d) "acyloxy" and "-o-<sup>o</sup>c-(CH<sub>2</sub>)<sub>n</sub>-<sup>o</sup>c-R<sub>9</sub>" and "-o-<sup>o</sup>c-R<sub>10</sub> in the definition of R<sub>6</sub> and R<sub>7</sub>; and

(e) "acyl" and "-<sup>o</sup>c-R<sub>14</sub>" in the definition of R<sub>6</sub> and R<sub>7</sub>.

6. The terms "acyl" and "acyloxy" are indefinite and otherwise not adequately supported by the enabling disclosure. The terms read on the residue of any organic acid and are ordinarily construed to include more than carboxylic acid residues.

7. The recitation of a broad range followed by a narrower embraced range ("such as") renders a claim indefinite as it is unclear whether the narrow range is restrictive as to the broad range.

8. The terms "alkyl" and "cycloalkyl" recited at the top of page 83 should recite carbon atom ranges.

9. The term "heterocyclic ring" is indefinite and otherwise not adequately supported by the enabling

disclosure. No limits are recited in the claim or in the specification. And the single listed group, N-methylpiperazine, is not deemed adequate to provide support for the multitudes of groups embraced by the term. Note also, In re Wiggins et al; 179 USPQ 421; and In re Fouche, 169 USPQ 429.

10. Composition claims should recite a specific intended use, not broadly "pharmaceutical". Composition claims should also recite an amount of active ingredient. While functional language is sufficient, it must be specific, not broadly "an effective amount". Same method of use claims. Note Ex parte Dobson, 165 USPQ 29.

11. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title. if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

12. Claims 1-6, 8, 13, 14 and 19-24 are rejected

under 35 U.S.C. 103 as being unpatentable over Newberry.

13. At column 2, line 10, formula VII, Newberry generically teaches 1,5-diarylpyrazoles wherein the 3-position is substituted by an aliphatic acid. The compounds are antinflammatory agents.

14. Generally, absent a showing of unexpected results, there is nothing unobvious in choosing "some" from among "many" indiscriminately. In re Lemkin, 141 USPQ 814.

15. The various methods are obvious over the prior art utility disclosure in view of Applicants' admission by way of the "Background" section that the art recognizes a correlation between the various uses.

16. Applicants are reminded that any rebuttal proof must be commensurate in scope with the claims. In re Greenfield, 197 USPQ 227.

17. Claims 1-6, 8, 13, 14 and 19-24 are rejected under 35 U.S.C. 103 as being unpatentable over Rainer.

18. Rainer discloses 1,3-diaryl-5-halopyrazole-4-acetic acids and their derivatives useful as analgetic, antipyretic, and antiphlogistic agents. The Rainer compounds differ from the claimed compounds in two ways. First, the Rainer compounds are position isomers of the claimed compounds. Second, in the Rainer compounds a methylene group separates the acid moiety from the pyrazole ring whereas in the claimed compounds the separation is by at least an ethylene group.

19. The Rainer compounds are sufficiently close in structure to the claimed compounds that one of ordinary skill in the art, given Rainer, would find the claimed compounds obvious.

20. Given the overlap in utility, the claimed compositions and methods are likewise obvious.

21. Claim 25 is rejected under 35 U.S.C. 103 as being unpatentable over Newberry.

22. Newberry discloses the reaction of an arylhydrazine with a 1-aryl-substituted alkyl-1,3-dione to prepare a 1,5-diarylpyrazole derivative. Note column 3, line 58, through column 4, line 56.

23. Applicants claim a specific process within the Newberry generic process. The logic of In re Lemin is seen as controlling. Note also, In re Durden et al. 226 USPQ 359.

24. Finally, Applicants cooperation is requested in securing the articles listed in the "Background" section. Also, any art not cited there that relates to the provisos both here and in the parent should be submitted. The Examiner notes that provisos (a) and (b) in the parent are not recited here.

25. Any inquiry concerning this communication should be directed to Kurt Briscoe at telephone number 703-557-3920.

*Alan L. Rotman*

Alan L. Rotman  
Examiner  
Art Unit 121

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